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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,874	02/06/2001	Iris Pecker	01/21603	8407

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EXAMINER
HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,874	PECKER ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97-101 and 119-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97-101 and 119-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of claims 97-101 and 107, cancellation of claims 71, 72, 92-96, 107-111 and 114-118 and the addition of new claims 119-127, in the paper of 1/2/2006, is acknowledged.

Claims 97-101 and 119-127 are at issue and are present for examination.

Applicants' arguments filed on 1/2/2006 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 119-122 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 119-122 are rejected under this statue because the recitations in these claims "wherein said heparanase protein comprises a polypeptide at least 96% (claim 119), 97% (claim 120), 98% (claim 121) and 99%(claim 122) homologous to SEQ ID

NO: 10" are not supported by the specification at the time of filing and are thus considered new matter.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 97-99 and 123-126 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein or preparation comprising said protein having the amino acid sequence of SEQ ID NO: 10, said protein having heparanase activity or being so cleavable so as to acquire said heparanase activity, does not reasonably provide enablement for any protein or preparation comprising said protein having heparanase activity or being so cleavable so as to acquire said heparanase activity, wherein said protein is merely 70% homologous to SEQ ID NO: 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was originally stated in the previous office actions, 10/3/2005 as it applied to previous claims 71, 72, 92-101 and 107-111. In response to this rejection applicants have cancelled claims 71, 72, 92-96, amended claims 97-100 and added new claims 123-126 and traverse the rejection as it applies to the new claims. Newly added claims 119-126 are included in the rejection for the same reasons previously stated for claims 71, 72, 92-100 and 107-111.

Applicants continue to traverse the rejection and submit a copy of the decision of the Board of Patent Appeals and Interferences in *Ex Parte Sun*. Applicants submit their interpretation of the decision in *Ex Parte Sun* and point out what applicants believe are an analogous situation or fact patterns between *Ex Parte Sun* and the instant application. Applicants submit that the claim in question in *Sun* relates to a polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO: 1 (which encodes a protein of 400 amino acids). Applicants submit that the Board summarizes and rejected the examiners position which is similar to the position taken by the examiner in the instant case, to those proteins having a mere 70% homology to SEQ ID NO: 10.

Applicants further point out that the Board noted that the specification of *Sun* as well as the instant applications specification provides an example for how to screen for activity and applicants submit that both specifications at the minimal provide a very general guidance about where to vary the protein.

Applicants further submit that they in fact provide even more guidance then was provided for in *Sun* and conclude that given the facts and rationale by the Board in the *Sun* case, that the instant rejection should be withdrawn.

Applicants complete traversal is acknowledged and has been carefully considered, however, continues to be found nonpersuasive on the basis that the current rejection is based consideration of the Wands factors. Those factors to be considered in determining whether undue experimentation is required, are summarized in In re

Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

While applicants have pointed applicant's interpreted similarities between the *Sun* application and the instant application, applicants are reminded that the two applications are two different applications and that the determination of those factors considered to be relevant to whether undue experimentation is required is specific to each application.

While applicants have provided some guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including those number of amino acid modifications of any heparanase having 95% homology to SEQ ID NO: 10, applicants have not provided sufficient guidance to enable those variants having greater than 95 % homology to SEQ ID NO: 10, for the reasons previously presented.

As previously stated, current techniques (i.e., high throughput mutagenesis and screening techniques) in the art would not allow for finding the few active mutants within the several hundred thousand to greater then several trillions of inactive mutants, as is the case for the claims limited to 70% identity. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the

direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any heparanase having a mere 70% homology to SEQ ID NO: 10. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 97-101 and 119-127 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuks et al. (U.S. Patent No. 5,362,641).

The rejection was originally stated in the previous office actions, 10/3/2005 as it applied to previous claims 71, 72, 92-101 and 107-111. In response to this rejection

applicants have cancelled claims 71, 72, 92-96, amended claims 97-101 and added new claims 119-127 and traverse the rejection as it applies to the new claims. Newly added claims 119-127 are included in the rejection for the same reasons previously stated for claims 71, 72, 92-101 and 107-111.

In applicant's traversal, applicants note that applicants have cancelled several claim sets and that the remaining claims all require that the recited preparation of heparanase be able to elicit anti-heparanase antibodies.

Applicants submit that the current action acknowledged (and concedes) what to what applicants have already declared "namely, that the preparation taught by Fuks could not elicit antiheparanase antibodies. Rather this preparation elicited anti-PAI-1 antibodies.

This argument is a continuation of that previously presented by applicants based on the argument that the antibodies raised in Fuks in an attempt to prepare anti-heparanase antibodies were actually anti-PAI-1 antibodies. As has been previously stated, this is acknowledged, however, it continues to be the position of the office that, though not 100% pure, the preparation taught by Fuks et al. is that of "an isolated heparanase", from the same source as applicants claimed heparanase protein, and thus Fuks et al. anticipates applicants claimed "isolated heparanase protein" for all of the reasons of record.

Applicants further argue that if the claims were to 90% purity and Fuks could only get its preparation to 80% purity, would the action then argue that Fuks somehow had

the potential to be 90% pure? Applicants submit that the circumstances are no different.

Applicants argument is appreciated but applicants logic is flawed, as a more relevant analogy would be that the claims were to that which is "capable of being purified to 90%", not "purified to 90%". In such a situation the same rejection would be applied based on the same logic.

Thus applicant's argument has been considered in full and found to be non-persuasive.

Remarks

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
4/4/2006